University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

26-Aug-2016

Kathryn A Davis
Kathryn.Davis@uphs.upenn.edu
Attn; Heather Gatens
gatens@seas.upenn.edu

PRINCIPAL INVESTIGATOR : Kathryn A Davis
TITLE : Localizing Epileptic Networks Using 3T MRI
SPONSORING AGENCY : No Sponsor Number
PROTOCOL # : 819126
REVIEW BOARD : IRB #7

Dear Dr. Davis:

The documents noted below, for the above-referenced protocol, were reviewed using the expedited procedure set forth in 45 CFR 46.110 and approved on 25-Aug-2016.

The following documents were included with this submission:
-HS-ERA Modification Submission (Confirmation Code: cbhhebia), submitted 08/22/16
-IRB Modification Form, dated 08/22/16
-Cover Letter, dated 08/22/16
-Grant Approval Letter (Virtual Resection to Treat Epilepsy, Grant #1R01NS099348) dated 01/25/16
-Email Correspondence (Re: IRB review of protocols for NIH grant funding), dated 08/22/16

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Stephanie Lesage

Digitally signed by Stephanie Lesage
Date: 2016.08.26 13:32:18 -04'00'

IRB Administrator

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

04-Nov-2015

Kathryn A Davis
c/o Carlos Coto
Sent via E-mail: Carlos.Coto@uphs.upenn.edu
Kathryn.Davis@uphs.upenn.edu

PRINCIPAL INVESTIGATOR	: Kathryn A Davis
TITLE	: Localizing Epileptic Networks Using 3T MRI
SPONSORING AGENCY	: NO SPONSOR NUMBER
PROTOCOL #	: 819126
REVIEW BOARD	: IRB #7

Dear Dr. Kathryn Davis:

The above referenced protocol was reviewed and re-approved using the expedited procedure set forth in 45 CFR 46.110(b) (3,4,5,7), on 11/3/2015.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for obtaining any relevant committee approvals.

This approval is for the period 03-Nov-2015 to 02-Nov-2016.

The following documents were included in this review:

- HS-ERA Continuing Review Submission, confirmation bjedbahi, submitted 11/01/2015
- Combined Informed Consent Form and HIPAA Authorization Form, dated 10/25/2013
- Penn/CHOP Agreement, uploaded 10/30/2015
- Vulnerable Populations: Children, uploaded 10/30/2015

The IRB reviewed and approved the Subpart D review as per Federal Regulations 45 CFR 46.404 (FDA 50.51), as the research was determined to be no greater than minimal risk. The IRB determined that permission of one parent is sufficient and that adequate provisions are made for soliciting permission. The IRB has determined that assent must be obtained from subjects and appropriately documented.

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

David Heagerty

Digitally signed by David Heagerty
DN: cn=David Heagerty, o=IRB, ou=ORA, email=heagerty@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this document
Date: 2015.11.04 14:17:53 -05'00'

IRB Administrator

CC: Children's Hospital of Philadelphia-3535 Market Street, Ste 1200

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

25-Aug-2016

Brian Litt
littb@mail.med.upenn.edu
Attn: Jacqueline Boccanfuso
jacb@seas.upenn.edu

PRINCIPAL INVESTIGATOR	: Brian Litt
TITLE	: The International Epilepsy Electrophysiology Database
SPONSORING AGENCY	: National Institute of Neurological Disorders and Stroke/NIH/DHHS
PROTOCOL #	: 811097
REVIEW BOARD	: IRB #4

Dear Dr. Litt:

The documents noted below, for the above-referenced protocol, were reviewed using the expedited procedure set forth in 45 CFR 46.110 and approved on 24-Aug-2016.

- HS-ERA Modification Submission, confirmation code: cbhhehda, submitted 8-22-16
- IRB Modification Form, submitted 8-22-16
- Cover Letter, dated 8-22-16
- NIH Funding Grant Application 1R01NS099348 for Project “Virtual Resection to Treat Epilepsy," dated 1.25.16
- Email Correspondence re: grant proposal review, dated 8-22-16

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Amanda O'Hara

Digitally signed by Amanda O'Hara
Reason: I attest to the accuracy and integrity of this document
Date: 2016.08.25 13:37:03 -04'00'

IRB Administrator

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

10-Aug-2016

Brian Litt
littb@mail.med.upenn.edu
Attn: Jacqueline Boccanfuso
jacb@seas.upenn.edu

PRINCIPAL INVESTIGATOR	: Brian Litt
TITLE	: The International Epilepsy Electrophysiology Database
SPONSORING AGENCY	: National Institute of Neurological Disorders and Stroke/NIH/DHHS
PROTOCOL #	: 811097
REVIEW BOARD	: IRB #4

Dear Dr. Litt:

The above referenced protocol was reviewed and re-approved using the expedited procedure set forth in 45 CFR 46.110(b) (4,5), on 09-Aug-2016.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for obtaining any relevant committee approvals.

This approval is for the period 09-Aug-2016 to 08-Aug-2017.

The following documents were included in this review:
-HS-ERA Continuing Review Submission, confirmation code: cbfjabdf, submitted 8-8-16
-Cover Letter, dated 8-8-16
-IRB Continuing Review Application, uploaded 8-8-16
-Combined Informed Consent and HIPAA Authorization Form, version dated 6-9-15
-CITI Completion Report for Eric Marsh, completion date 12-10-15
-Neuralynx User's Manual, dated 12-17-07
-Progress Report, dated 7-25-16

Please note: At the time of the next modification, please remove Personal Info **from the personnel tab in HS-ERA. Since they are only accessing de-identified data, this does not qualify as research with human subjects.**

Please note: As this study appears to utilize directly-identifiable protected health information (PHI), please review the new electronic data protection requirements for research involving the use of protected health information available at http://www.upenn.edu/IRB/initial-review.If your current confidentiality plan does not align with these requirements, please submit a modification to update your plan. Any changes should be reflected in the HSERA Application, as well as any related protocol documents.

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Stephanie Lesage
Digitally signed by Stephanie Lesage
Date: 2016.08.10 15:27:21 -04'00'

IRB Administrator

University of Pennsylvania
Institutional Review Board
3800 Spruce St., First Floor Suite 151
Philadelphia, PA 19104
Ph: 215-573-2540
(Federalwide Assurance # 00004028)

11-Oct-2017

Kathryn A Davis
c/o Heather Gatens
gatens@seas.upenn.edu
Kathryn.Davis@uphs.upenn.edu
irbcorr@chop.edu

PRINCIPAL INVESTIGATOR : Kathryn A Davis
TITLE : Localizing Epileptic Networks Using 3T MRI
SPONSORING AGENCY : NO SPONSOR NUMBER
PROTOCOL # : 819126
REVIEW BOARD : IRB #7

Dear Dr. Davis:

The above referenced protocol was reviewed and re-approved using the expedited procedure set forth in 45 CFR 46.110(b) (3,4,5,7), on 10-Oct-2017.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for obtaining any relevant committee approvals.

This approval is for the period 10-Oct-2017 to 09-Oct-2018.

The documents included with the application noted below are approved:

- HS-ERA Continuing Review Submission, confirmation ceicefhd, submitted 10/04/2017

Attention: During the review of this submission it was noted that human research CITI training for Personal Info **is either expired or improperly documented. Please instruct this person to submit a valid report of completion to the IRB CITI helpdesk (IRBCITIsupport@lists.upenn.edu). They should not be engaged in any human research activity until confirmation of approval from the CITI help desk has been received via email.**

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Christy Hullings

Digitally signed by Christy Hullings
Reason: I attest to the accuracy and integrity of this document
Date: 2017.10.11 15:44:23 -04'00'

IRB Administrator

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT & HIPAA AUTHORIZATION FORM

Title of Research Study: Localizing Epileptic Networks Using 3T MRI

Protocol Number: 819126

Principal Investigator:

Kathryn Davis, M.D.
Neurology Department
3 W. Gates Building
3400 Spruce St.
Philadelphia, PA 19104
Phone: 215-349-5166
Pager/cell: Personal Info
Fax: 215-349-5733

Emergency Contact: (215) 662-4552 (Ask for the epilepsy physician on call)

You, or your child, are being asked to take part in a research study. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family. If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

I. What is the purpose of the study?

The purpose of this research study is to study the capabilities of new methods for studying the brain using Magnetic Resonance Imaging (MRI). MRI already provides detailed images of brain anatomy, but newer methods including new MRI techniques and magnetic resonance spectroscopy expand this capability. These new MRI methods will not require any invasive procedures. If successful, these new methods will expand the information, which can be obtained from MRI studies of the brain in patients with epilepsy.

 IRB Approval From: 10/10/2017 To: 10/09/2018

II. Why was I asked to participate in the study?

You are being asked to participate in a research study at the University of Pennsylvania because you are a presurgical epilepsy patient or are a healthy volunteer without epilepsy. This study uses magnetic resonance imaging (MRI). The background information concerning the study, risks and inconveniences are reviewed below. Please ask any questions you may have about this study.

III. How long will I be in the study? How many other people will be in the study?

The duration of the entire study, including subject recruitment and data analysis, will be ongoing from the date of institutional approval. Once enrolled, your actual participation in the study each visit will be limited to the time it takes to undergo the consent process and MRI scans (about 90 minutes). Subjects with epilepsy may be asked to return for additional MRI scans pre and post operatively, up to four scans/visits total (minimum of 180 minutes and maximum of 360 minutes total time commitment if they agree to do additional scans). At each visit, subjects with epilepsy may be asked to complete the Computerized Neurocognitive Battery (CNB), Montreal Cognitive Assessment (MoCA), Beck Depression Inventory, and Beck Anxiety Inventory in addition to the MRI scan. If the patient agrees, total visit time will be around 3 hours.

IV. Where will the study take place?

The study will be conducted on MRI scanners dedicated to research at the University of Pennsylvania. The study will be performed using a standard MRI scanner operating at 3.0 Tesla.

V. What will I be asked to do?

After reading, understanding and signing this document, you will be asked to remove all metal objects from your clothing. If you have any metal devices inside your body, like a pacemaker or a vagal nerve stimulator, you will not be allowed to be in the study. After this step, you will be asked to lie on a specially designed bed and a cylindrical or circular antenna will be placed around the part of your body under investigation.

The antenna works much like the antenna on your radio except it can both transmit as well as receive radio waves. This antenna may be experimental and may have been designed and constructed at the University of Pennsylvania. You will be given earplugs to wear to dampen the banging noise caused by the imaging process. The earplugs do not block out all sound since we wish to stay in communication with you at all times.

You will then be moved into the magnet, a large hollow cylinder, until the part of your body under investigation is at the center. The study will then proceed. The MR operator will inform you of the progress of the study and prepare you for each sequence of banging noises you will hear. You will need to keep perfectly still during the imaging acquisition. The entire procedure will take on average 60 minutes but will not exceed 90 minutes. If are willing to and time permits, we may ask you to undergo a second MRI during a time of known seizure

clustering and a MRI during a non-cluster time period for about another hour.

When the study is complete, you will be moved out of the magnet. We ask that you please get up slowly since you will have been lying still for a relatively lengthy period of time.

During the study a neurologist will be available for any medical questions or problems. The technicians involved in the study will advise you on the progress of the study. If at any time you feel uncomfortable, no matter what the reason, the study will immediately be stopped.

After completion of the scan, you may be asked to complete the Computerized Neurocognitive Battery (CNB), Montreal Cognitive Assessment (MoCA), Beck Depression Inventory, and Beck Anxiety Inventory.

The CNB takes approximately 1.5 hours and is designed to test cognition in a variety of areas by using short tasks administered on a computer using either a mouse or keyboard to record responses. Most of these tasks will have a brief training period before responses are recorded. A research assistant will read instructions for each test and observe the participant as they complete the tests. For each test, accuracy and speed are computed.

The Beck Depression Inventory is a 21-question self report tool used to assess the symptoms and severity of symptoms of depression. It takes approximately 5 minutes to complete. You will read each of the statements and circle the option that is most consistent with your experience.

The Beck Anxiety Inventory is a 21-question self report tool used to assess the severity of symptoms of anxiety. It takes approximately 5 minutes to complete. You will read each of the statements and circle the option that is most consistent with your experience.

The Montreal Cognitive Assessment (MoCA) is a one page test that is used to assess several cognitive domains. It takes approximately 10 minutes to complete. The research assistant will ask you to perform a series of 11 cognitive tasks and will record your responses.

VI. What are the risks?

The following circumstances may indicate that you are <u>not eligible</u> for this study:

- You have had surgery where metal has been placed in your body,
- There is metal in your body due to accident or injury,
- You have done metal work, grinding, or worked in a situation where you could have gotten metal in your eyes,
- You have had an injury to your eyes,
- You are a female who has tested positive on a pregnancy test.

The known risks associated with this study are minimal. However, MRI machines produce loud banging noises, which cause some people to become stressed or upset. You may feel uncomfortable inside the magnet if you do not like to be inside small places or have difficulty lying still. The greatest risk is a metallic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the

study remove all metal from their clothing and all metal objects from their pockets. No metal objects are allowed to be brought into the magnet room at any time. Subjects with pacemakers or vagal nerve stimulators will be automatically excluded from participating in this study.

In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the magnet room. In the event that an accident or incident of any kind should occur while you are in the MRI scanner, designated members of the research team are trained in calling 911 and know how to activate the emergency system in the University. Some of the pulse sequences and/or RF coils are not FDA approved but are considered to pose no more than minimal risk.

Although there are no known risks of MRI to pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women. All female subjects will be asked if there is a possibility they may be pregnant prior to being scanned.

For the children in this study, if you believe there is a possibility you could be pregnant, this will not be shared with your parent(s). However, we strongly encourage you to share your concerns with your parents. If you do believe there is a possibility you could be pregnant, you will not be able to continue participation in the study.

There are no significant risks involved in taking the CNB. The rating and functioning scales are innocuous. The ratings and functioning measures as well as the CNB my cause boredom, fatigue, and/or increased stress and anxiety, but probably no more so than is experienced in everyday living.

There may be loss of confidentiality as it cannot be guaranteed.

Incidental Findings

It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

VII. How will I benefit from the study?

There is no direct benefit from participation in this study.

VIII. What happens if I do not choose to join the research study?

If you are currently receiving medical services and you choose not to volunteer in the research study, your services will continue.

IX. Will I have to pay for anything?

There is no cost to you to participate in this study.

X. Will I be paid for being in this study?

Both patients and control subjects will be paid $50 for MRI. If you subject complete more than one scan, you will receive $50 for each scan day that you participate in this study. Patients will be paid an additional $25 for completing the CNB, MoCA, and Beck Depression and Anxiety Inventories for each visit.

Participants will be paid either through a mailed check or a prepaid card. The prepaid card is managed by the Greenphire ClinCard Reimbursement Program.

Greenphire is a company working together with the study sponsor to manage your compensation. You will be issued a Greenphire ClinCard, which works like a debit card. When a visit is completed, funds will be approved and loaded onto your card. The funds will be available within 1 business day and can be used at your discretion. You will be issued one card for the duration of your participation. In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you from your study doctor, including your *name, address and date of birth.*

All information about you is stored in a secure fashion and is deleted from Greenphire's system once the study has been completed. Your information will not be shared with any third parties (including the study sponsor) and will be kept completely confidential.

By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up payments. You agree that the information you provide is used by Greenphire to perform reimbursement payments to you.

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program.

XI. What happens if I am injured or hurt during the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.
If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

XII. When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by the study

 IRB Approval From: 10/10/2017 To: 10/09/2018

doctor, the Food and Drug Administration (FDA), or the University of Pennsylvania Institutional Review Board (IRB, the committee charged with the overseeing research on human subjects) without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

XIII. Who can see or use my information? How will my personal information be protected?

1. Personal health information about you that will be collected in this study. The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study:

- Name
- Address
- Phone number
- Medical record number
- Medical history
- Current and past medications or therapies
- Social Security Numbers
- Data and measurements generated from the tests and procedures (MRI) described earlier in this document
- EEG, MRI, SPECT, PET, MEG, WADA, and neuropsychological testing data used to localize seizure focus and characterize cognitive status
- Seizure status after surgery and surgical pathology results

Computerized Neuropsychological Battery, Beck Depression Inventory, Beck Anxiety Inventory, and Montreal Cognitive Assessment data will be linked to patient names and outcomes although all data will be deidentified for analysis and reporting. All subject data will only be accessible by IRB approved research personnel. All information will be kept in locked research offices and on password protected computers. Paper copies of files will be kept in a locked storage cabinet.

2. Why your personal health information is being used?

Your personal contact information is important for the University of Pennsylvania Health System and School of Medicine study team to contact you during the study. Your health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care. The Principal Investigator may also use the results of these tests and procedures to treat you.

 IRB Approval From: 10/10/2017 To: 10/09/2018

3. The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other University staff associated with the study)
- Authorized investigators of other research labs conducting similar studies within the University of Pennsylvania and the Children's Hospital of Philadelphia who may collaborate with the Principal Investigator could see deidentified data from MRI scans.
- The University of Pennsylvania and Children's Hospital of Philadelphia's Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties, for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.

4. Who, outside of the University of Pennsylvania Health System and the School of Medicine, might receive your personal health information?

- As part of the study the Principle Investigator, study team and others listed above in item number 3, may disclose your personal health information, including the results of the research study tests and procedures to the following:
- Government agency and/or their representative: The Food and Drug Administration (FDA) is the governing agency that regulates clinical research in the United States. The Principle Investigator or study team will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System or School of Medicine the information may no longer be covered by the federal privacy protection regulations. In all disclosures outside of the University of Pennsylvania Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law.

5. How long will the University of Pennsylvania Health System and the School of Medicine be able to use or disclose your personal health information?

- Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of Pennsylvania Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. Results of all tests and procedures performed solely for this research study and not as part of your regular care will not be included in your medical record.
- Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless you have given written authorization, the University of

Pennsylvania's Institutional Review Board grants permission, or as permitted by law.

6. Access to your records

You will be able to request access to your medical record when the study is completed. During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

7. Changing your mind

You may withdraw from the study for any reason simply by explaining this to the Principal investigator or a member of the study team. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care. You may also withdraw your permission for the use and disclosure of any of your personal information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

8. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

XIV. Who can I call about my rights as a research subject?

If you have questions regarding your participation in this research study or if you have any questions about your rights as a research subject don't hesitate to speak with the Principal Investigator listed on page one of this form. Concerning your rights as a research subject, you may also contact the Office of Regulatory Affairs at the University of Pennsylvania by calling (215) 898-2614.

XV. Conclusion

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System, the School of Medicine, and (if applicable) the Children's Hospital of Philadelphia to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System, the School of Medicine, and (if applicable) the Children's Hospital of Philadelphia to disclose that personal health information to outside organizations or people involved with the operations of this study. A copy of this consent form will be given to you.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

For children ages 10-17, both parental/guardian permission and assent from the child is required for the child to participate in the study. The child can decide not to participate even if the parent/guardian gives permission. In addition to the parent/guardian signing the consent form, the child will be asked to sign a separate assent form.

Combined Informed Consent Form and HIPAA Authorization (for Adults 18 and Older)/ Parental Permission Form (for Children ages 10-17) and Assent Form (for Children ages 10-17)

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

_____
Name of Subject (Please Print)

_____ _____
Signature of Subject Date
(18 years or older and competent to consent)

_____ _____
Name of Authorized Representative Relation to subject
(for children ages 10-17, Please Print) (parent, legal guardian)

_____ _____
Signature of Authorized Representative Date

_____
Name of Person Obtaining Consent (Please Print)

_____ _____
Signature of Person Obtaining Consent Date

 IRB Approval From: 10/10/2017 To: 10/09/2018

Child Assent (ages 10-17) to Take Part in this Research Study

I have explained this study and the procedures involved _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Name of Person Obtaining Consent (Please Print)

_____ _____
Signature of Person Obtaining Consent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date

 IRB Approval From: 10/10/2017 To: 10/09/2018

University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

27-Jul-2017

Brian Litt
c/o Jacqueline Boccanfuso
jacb@seas.upenn.edu
littb@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR	: Brian Litt
TITLE	: The International Epilepsy Electrophysiology Database
SPONSORING AGENCY	: National Institute of Neurological Disorders and Stroke/NIH/DHHS
PROTOCOL #	: 811097
REVIEW BOARD	: IRB #4

Dear Dr. Litt:

The above referenced protocol was reviewed and re-approved using the expedited procedure set forth in 45 CFR 46.110(b) (4,5), on 26-Jul-2017.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. You are responsible for obtaining any relevant committee approvals.

This approval is for the period 26-Jul-2017 to 25-Jul-2018.

The documents included with the application noted below are approved:

- HS-ERA Continuing Review Submission, confirmation cebiahcj, submitted 07/26/2017

Note: At the time of next modification, please remove Personal Info **from the personnel list as their activity was previously confirmed to not constitute human subjects research. If they are to remain associated with the protocol, please instruct them to submit a valid report of completion to the IRB CITI helpdesk (IRBCITIsupport@lists.upenn.edu). They should not be engaged in any human research activity until confirmation of approval from the CITI help desk has been received via email.**

Attention: During the review of this submission it was noted that human research CITI training for Liberty Simmons is either expired or improperly documented. Please instruct them to submit a valid report of completion to the IRB CITI helpdesk (IRBCITIsupport@lists.upenn.edu). They should not be engaged in any human research activity until confirmation of approval from the CITI help desk has been received via email.

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Stephanie Lesage

Digitally signed by Stephanie Lesage
Date: 2017.07.28 13:38:33 -04'00'

IRB Administrator